

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0009

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

NOVARTIS PHARMACEUTICALS CORPORATION
BLDG 437/1329 ONE HEALTH PLAZA

EAST HANOVER, NJ 07936

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	54	433	40	10	483
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	12	0	12
7. Hamsters	0	0	0	0	0
8. Rabbits	4	48	159	1	208
9. Non-human Primates	124	427	12	11	450
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
28-FEB-2014

(b)(6), (b)(7)(c)

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Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0012

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

ETHICON INC
P O BOX 151
RT 22 WEST
SOMERVILLE, NJ 08876

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	5	0	5
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	4	0	108	0	108
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	5	0	5
11. Pigs	0	0	295	1	296
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
27-JAN-2014

(b)(6), (b)(7)(c)

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Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0013

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

WORLDWIDE MOBILE VETERINARY UNIT
8 FOXHUNT DRIVE

ROCKAWAY, NJ 07866

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	43	0	43
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
12-DEC-2013

(b)(6), (b)(7)(c)

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No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0020

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY
185 S ORANGE AVENUE MSB A-604

NEWARK, NJ 07103

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	8	0	8
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	26	0	26
7. Hamsters	0	46	26	0	72
8. Rabbits	25	42	146	0	188
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	81	0	81
12. Other Farm Animals					
13. Other Animals	0	4	32	0	36

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
16-DEC-2013

(b)(6), (b)(7)(c)

OMB APPROVED
0579-0036

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

1. REGISTRATION NUMBER
22-R-0020

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY
185 S ORANGE AVENUE MSB A-604

NEWARK, NJ 07103

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

[illegible]

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED _____

16-DEC-2013

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Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0022

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

PRINCETON UNIVERSITY
P O BOX 36

PRINCETON, NJ 08544

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	3	0	0	3
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	2	36	9	0	45
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
31-JAN-2014

(b)(6), (b)(7)(c)

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No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0025

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

RUTGERS STATE UNIVERSITY OF N J
604 ALLISON RD

PISCATAWAY, NJ 08854

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

NELSON 3559 BUSCH CAMP

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	2	12	76	0	88
7. Hamsters	0	0	0	0	0
8. Rabbits	1	14	16	0	30
9. Non-human Primates	0	0	10	0	10
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
10-DEC-2013

(b)(6), (b)(7)(c)

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Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0028

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

BRISTOL MYERS SQUIBB COMPANY
P.O. BOX 4000 D24-09

PRINCETON, NJ 08543

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

BRISTOL MYERS SQUIBB COMPANY

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

BRISTOL MYERS SQUIBB COMPANY
GENZYME TRANSGENICS CORP (GOATS FOR
EXPERIMENTAL STATION

Animals Covered By The Animal Welfare Regulations	Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	314	237	22	573
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	58	82	0	140
7. Hamsters	0	13	103	0	116
8. Rabbits	15	66	495	0	561
9. Non-human Primates	347	619	503	10	1132
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	1	23	0	0	23

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
28-JAN-2014

(b)(6), (b)(7)(c)

OMB APPROVED
0579-0036

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

1. REGISTRATION NUMBER
22-R-0028

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

BRISTOL MYERS SQUIBB COMPANY
P.O. BOX 4000 D24-09

PRINCETON, NJ 08543

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

[illegible]

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED _____

28-JAN-2014

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0032

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

HOFFMANN-LA ROCHE INC
RSCH & DEV DIV, 340 KINGSLAND ST

NUTLEY, NJ 07110

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	80	0	0	80
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	64	0	0	64
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
26-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0036

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

MERCK SHARP & DOHME CORP
126 EAST LINCOLN AVENUE
RY33-512
RAHWAY, NJ 07065

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

SCHERING-PLOUGH RESEARCH INST.

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	79	648	289	1	938
5. Cats	0	0	0	0	0
6. Guinea Pigs	36	959	835	7	1801
7. Hamsters	491	1757	618	473	2848
8. Rabbits	307	1773	501	10	2284
9. Non-human Primates	118	1013	514	10	1537
10. Sheep	0	0	0	0	0
11. Pigs	0	9	21	0	30
12. Other Farm Animals					
13. Other Animals	0	0	446	0	446

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
01-MAY-2014

(b)(6), (b)(7)(c)

OMB APPROVED
0579-0036

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

1. REGISTRATION NUMBER
22-R-0036

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

MERCK SHARP & DOHME CORP
126 EAST LINCOLN AVENUE
RY33-512
RAHWAY, NJ 07065

[illegible]

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)(c)

DATE SIGNED _____

01-MAY-2014

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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0040

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

ENVIGO C R S INC
P.O. BOX 2360

EAST MILLSTONE, NJ 08875

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	37	604	89	38	731
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	3	100	1	0	101
9. Non-human Primates	4	305	43	18	366
10. Sheep	0	0	0	0	0
11. Pigs	0	278	61	17	356
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
27-JAN-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0041

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

BECTON DICKINSON AND CO
ONE BECTON DRIVE

FRANKLIN LAKES, NJ 07417

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	83	420	0	503
7. Hamsters	0	0	0	0	0
8. Rabbits	0	192	6	0	198
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	81	0	81
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
26-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0064

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

ORTHO CLINICAL DIAGNOSTICS INC
MANUFACTURING
1001 U S HIGHWAY 202
RARITAN, NJ 08869

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	139	243	0	382
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
21-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0066

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

UNIVERSITY OF MEDICINE & DENTISTRY OF NJ
675 HOES LANE

PISCATAWAY, NJ 08854

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	6	0	6
11. Pigs	0	0	2	0	2
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
21-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0069

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

CONSUMER PRODUCT TESTING CO INC
70 NEW DUTCH LANE

FAIRFIELD, NJ 07004

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	1048	34	0	1082
7. Hamsters	0	12	0	0	12
8. Rabbits	12	431	13	0	444
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
12-DEC-2013

(b)(6), (b)(7)(c)

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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0076

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

CAMDEN COUNTY COLLEGE
P O BOX 200
COLLEGE DRIVE
BLACKWOOD, NJ 08012

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	8	0	8
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
26-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0099

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

UNIVERSITY OF MEDICINE & DENTISTRY
ROWAN UNIVERSITY
201 MULLICA HILL RD
GLASSBORO, NJ 08028

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
12-DEC-2013

(b)(6), (b)(7)(c)

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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0130

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

QUALTECH LABORATORIES, INC.
104 GREEN GROVE ROAD

OCEAN, NJ 07712

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	3	0	3
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	6	0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
16-DEC-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0138

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

JANSSEN RESEARCH AND DEVELOPMENT L L C
P O BOX 300 ROUTE 202 SOUTH

RARITAN, NJ 08869

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	23	129	7	51	187
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	30	0	30
7. Hamsters	0	0	0	0	0
8. Rabbits	0	4	8	0	12
9. Non-human Primates	7	0	25	0	25
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
31-JAN-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0140

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

BERGEN COMMUNITY COLLEGE
400 PARAMUS RD

PARAMUS, NJ 07652

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	32	0	32
5. Cats	0	0	1	0	1
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	6	0	0	6
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
01-MAY-2014

(b)(6), (b)(7)(c)

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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0143

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

PRODUCT SAFETY LABS
2394 U S HIGHWAY 130

DAYTON, NJ 08810

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	3365	17	609	3991
7. Hamsters	0	118	0	0	118
8. Rabbits	0	782	880	0	1662
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
31-JAN-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0144

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

INTERVET INC
2 GIRALDA FARMS

MADISON, NJ 07940

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

INTERVET INC

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	246	865	137	5	1007
5. Cats	21	223	6	0	229
6. Guinea Pigs	5	742	948	752	2442
7. Hamsters	265	5364	2153	959	8476
8. Rabbits	7	32	66	0	98
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
18-FEB-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

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Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0146

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

HACKENSACK UNIVERSITY MEDICAL CENTER
INSTITUTE FOR BIOMEDICAL RESEARCH
DAVID JOSEPH JURIST RESEARCH BLDG 30 PROSPECT AVE
HACKENSACK, NJ 07601

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	12	0	367	0	367
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
26-NOV-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0147

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

BARTONS WEST END FARMS INC
576 TOWNSBURY ROAD

GREAT MEADOWS, NJ 07838

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	3	0	3
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	16	0	16
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	46	0	46
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
10-DEC-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0148

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

INVIVOTEK
17 BLACK FOREST RD

HAMILTON, NJ 08691

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	2	141	181	324
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
30-JAN-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0149

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

ZOETIS INC
100 Campus Drive

FLORHAM PARK, NJ 07932

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	40	318	635	33	986
5. Cats	12	215	76	2	293
6. Guinea Pigs	128	2374	201	282	2857
7. Hamsters	90	12866	2089	3214	18169
8. Rabbits	178	56	1841	0	1897
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals	0	1059	70	64	1193

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
30-JAN-2014

(b)(6), (b)(7)(c)

OMB APPROVED
0579-0036

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

1. REGISTRATION NUMBER
22-R-0149

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

ZOETIS INC
100 Campus Drive

FLORHAM PARK, NJ 07932

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use this form.)

[illegible]

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(b)(6), (b)(7)(c)

DATE SIGNED _____

30-JAN-2014

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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0150

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

PEDIATRIC CARDIOLOGY P A
137 PAVILION AVENUE

LONG BRANCH, NJ 07740

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	2	2	0	4
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
03-FEB-2014

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-R-0151

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

COOPER MEDICAL SCHOOL OF ROWAN UNIVERSITY
401 S BROADWAY
OFFICE # 630
CAMDEN, NJ 08103

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED
10-DEC-2013

(b)(6), (b)(7)(c)

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year 2013

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NUMBER
22-V-0003

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

VA MEDICAL CENTER 561
385 TREMONT AVENUE

EAST ORANGE, NJ 07018

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	30	0	30
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- Each principal investigator has considered alternatives to painful procedures.
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O.

NAME AND TITLE OF C.E.O. OR I.O. (Type or Print)

DATE SIGNED

(b)(6), (b)(7)(c)

Category E Explanation Form - Registration 22-R-0009

Novartis Pharmaceuticals Corporation

Species	Number of animals in Category E	Explain the procedure producing pain and/or distress.	Provide scientific justification why pain and/or distress could not be relieved	What, if any, federal regulations require this procedure?
Rabbit	1	This animal was dosed with a pharmaceutical compound (b) (4)	1	2a
Canine	10	These animals were dosed with a pharmaceutical compound (b) (4)	1	2a
Nonhuman Primate	11	These animals were dosed with a pharmaceutical compound (b) (4)	1	2a

b4

Column E Explanation

1. Registration Number: 22-R-0012
2. Number of Animals impacted: 1
3. Species of Animals used in the study: Swine
4. Explain the procedure producing pain and/or distress

Animal 18693 was part of a colorectal study (13-0200) where an enema was administered prior to the day of surgery. The personnel administering the enemas were well- trained and had experience performing this procedure. The animal became quiet and recumbent approximately three hours after the enema was given. This animal was checked by a veterinarian and given antibiotics and pain relief preventatively at this time. The next morning the animal seemed to be in discomfort and had an elevated temperature. It was decided that the animal should be euthanatized due to the high suspicion for rectal tear and possible peritonitis. The animal was euthanatized immediately. At necropsy, a rectal tear was confirmed. The animal was placed in the E category due to the time lag of approximately 1.5 hours between the end of the therapeutic effects of the pain relief and euthanasia.

This incident was not a part of the planned protocol and permission for euthanasia was obtained immediately.

This event was not part of a planned study but was the unexpected result of a preparatory procedure with which there is some inherent risk.

5. There was no scientific justification why pain and/or distress could not be relieved. Analgesics were administered and euthanasia was performed. There was a lag of 1.5 hours between the two.
6. There were no federal regulations requiring the procedure.

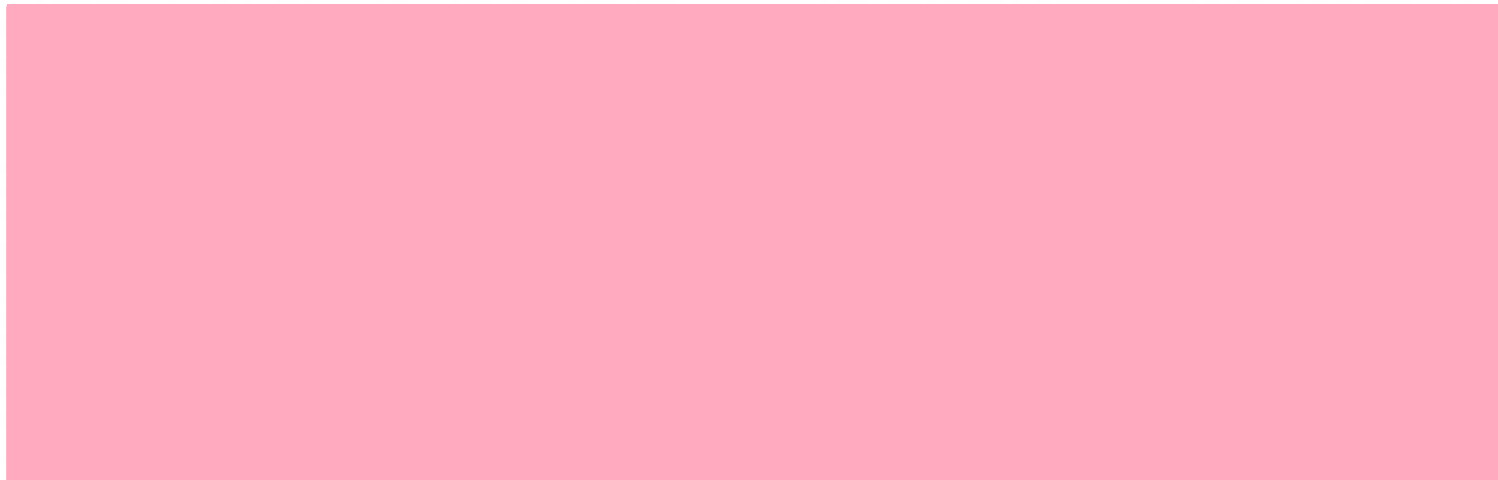
Appendix 1

BMS Explanation of Animals Listed as Column E – APHIS Form 7023 for 2013
Customer # 168; Research Facility Certificate # 22-R-0028



Appendix 1

BMS Explanation of Animals Listed as Column E – APHIS Form 7023 for 2013
Customer # 168; Research Facility Certificate # 22-R-0028



A. Column E Explanation (all studies listed below were approved by the IACUC at their respective site):

One rabbit developed signs of weight loss and inactivity while on an efficacy study. A decision was made to euthanize the rabbit, but the animal died before euthanasia could be performed.

Nine rabbits developed acute terminal complications while on toxicology studies. The acute nature of the complications did not allow time for euthanasia.

Six guinea pigs developed acute terminal complications while on product release testing studies for vaccines and biologics.

One guinea pig on a vaccine study developed acute terminal complications related to precaval blood collection.

Four hundred and seventy three hamsters developed terminal complications as part of an infectious disease study. The animals were closely monitored and those animals identified with significant health issues were humanely euthanized. The animals being reported died after a sudden onset of the disease before euthanasia could be accomplished.

One dog developed acute complications while on a toxicology study and died before euthanasia could be accomplished.

One non-human primate developed complications related to the test compound while on an investigative neuroscience study. The animal was given symptomatic medical treatment, but died.

Five nonhuman primates developed acute complications while on a toxicology study and died before euthanasia could be accomplished.

Four nonhuman primates developed clinical signs of decreased activity and weight loss while on a toxicology study and were euthanized.

A) Explanation of Category E Studies

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify pre-clinical testing requirements necessary for approval of new drugs. Specific regulations and/or guidelines include the following:

- International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use; Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1) June 2011
- ICH M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals
- ICH S3A Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies
- ICH Guidance: Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) (S4A)
- European OECD Guidelines for the Testing of Chemicals

Species	Number of Category E Animals	Description
Dogs	20	Animals were exposed to test article via oral administration. Twenty dogs exhibited neurological effects. Two dogs were humanely euthanized and the remaining 18 dogs recovered.
Dogs	1	Animals were exposed to test article via oral administration. One dog exhibited adverse gastrointestinal effects and was humanely euthanized.
Dogs	1	Animals were exposed to test article via oral tablet. One dog exhibited adverse gastrointestinal effects which resolved spontaneously with no treatment intervention.
Dogs	3	Animals were exposed to test article via oral gavage. Three dogs exhibited adverse neurologic signs. All 3 dogs were humanely euthanized.
Dogs	2	Animals were exposed to test article via oral gavage. Two dogs exhibited adverse gastrointestinal signs. Both dogs were humanely euthanized.

**Annual Report of Research Facility
October 1, 2012 to September 30, 2013
Huntingdon Life Sciences
Registration Number 22-R-0040**

NOV 19 2013

Species	Number of Category E Animals	Description
Dogs	2	Animals were exposed to test article via oral administration. Two dogs exhibited adverse gastrointestinal effects and were humanely euthanized.
Dogs	2	Animals were exposed to test article via intravenous administration. Two dogs exhibited adverse gastrointestinal effects and were humanely euthanized.
Dogs	2	Animals were exposed to test article via intravenous administration. Two dogs exhibited general malaise that could not be attributed to any specific target/organ system. These signs resolved spontaneously when test article administration was discontinued.
Dogs	2	Animals were exposed to test article via intravenous administration. Two dogs exhibited general malaise that could not be attributed to any specific target/organ system. These signs resolved spontaneously without any treatment intervention.
Dogs	3	Animals were exposed to test article via intravenous administration. Three dogs exhibited general malaise that could not be attributed to any specific target/organ system. These signs spontaneously resolved without any treatment intervention in 2 dogs. The third dog was humanely euthanized.
Monkeys	3	Animals were exposed to test article via oral administration. . Three monkeys exhibited general malaise that could not be attributed to any specific target/organ system. All three monkeys were humanely euthanized.
Monkeys	4	Animals were exposed to test article via oral administration. Four monkeys exhibited general malaise that could not be attributed to any specific target/organ system. All four monkeys were humanely euthanized.
Monkeys	7	Animals were exposed to test article via oral administration. Seven monkeys exhibited adverse neurologic effects. Of these 7 monkeys, 5 spontaneously recovered and 2 were euthanized.
Monkeys	4	Animals were exposed to test article via intravenous administration. Four monkeys exhibited adverse neurologic effects. Dosing was discontinued in all 4 of these monkeys.

Annual Report of Research Facility
October 1, 2012 to September 30, 2013
Huntingdon Life Sciences
Registration Number 22-R-0040

NOV 19 2013

Species	Number of Category E Animals	Description
Pigs	1	Animals were exposed to test article via oral administration. One pig exhibited adverse neurologic effects that spontaneously resolved with no treatment intervention.
Pigs	1	Animals were exposed to test article via oral administration. One pig exhibited adverse neurologic effects. This pig was humanely euthanized.
Pigs	1	Animals were exposed to test article via dermal administration. One pig exhibited adverse dermal effects. Dosing was discontinued in this pig.
Pigs	8	Animals were exposed to test article via oral administration. Eight pigs exhibited adverse neurologic effects. Of those 8 pigs, 4 were euthanized, and effects resolved when dose was adjusted in remaining 4 pigs.
Pigs	6	Animals were exposed to test article via dermal administration. Six pigs exhibited adverse dermal effects. Dose was discontinued in all 6 pigs.

Appendix 1
USDA ANNUAL REPORT (2012-2013)

Registration #: 22-R-0138

Species/protocol	Cat E usage	Procedure/Justification
Dogs	51	<p>Single and repeat dose (IV, Oral) Pharmacokinetic/Toxicology studies.</p> <p><i>These dogs experienced at least three slight to severe events of soft stool +/- emesis, after being dosed with Test compound.</i></p> <p>Analgesics cannot be administered as they may potentially interfere with the goals/aims of the intended studies, primarily study of the physiologic and pathologic processes produced by toxicity of dosed investigational agents. These studies are performed in accord with "Harmonization of Guidelines for Toxicity testing of Pharmaceuticals by 1992," regulatory Toxicology and Pharmacology, Vol 12, 179-211 (1990).</p> <p><i>(In all cases, this met the IACUC approved study endpoint criteria)</i></p>

Exemptions: none

Product Safety Labs

Registration Number: 22-R-0143

Attachment to USDA/APHIS Annual Report of Research facility

Explanation of Column "E" Entries.

10/01/12 through 9/30/13

609 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600):

These six hundred and nine (609) animals were used for Magnusson & Kligman method studies and exhibited eschar and/or corrosion or blanching at the dose site, which may indicate necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was $\leq 1 \text{ in}^2$. Use of topical anesthetic agents during dermal irritation tests is deemed inappropriate as it could lead to study complications such as delayed healing of the test site and likely impact the level of irritation (increase or decrease) which would result in questionable results. The use of analgesics in these particular studies would be inappropriate as well due to the resultant potential anti-inflammatory effects that could mask the indicators of irritation. The use of either of these agents could significantly compromise the results of the study.

Category E Explanations**Registration Number:** 22-R-0144**Number of hamsters:** 959**Species (common name):** Hamsters of animals used in the study.**Explain the procedure producing pain and/or distress**

The 959 hamsters listed in column E were used in the regulatory required potency testing of bacterial vaccines and for the development of an in vitro testing validation to reduce animal use. The potency testing, conducted as required by Federal regulations, caused depression and discomfort in the hamsters.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The effects of analgesic medication on the length and severity of the disease are not known; thus, use of analgesic medications would invalidate the scientific value of the potency tests. For this reason, neither the USDA/CVB nor our company uses any medications to relieve pain and distress. The USDA/CVB regulations do not allow the use of any other standard potency test for the release of these vaccine serials, as no alternative potency test has been validated and accepted by the USDA/CVB. Distress/discomfort caused by these tests has been substantially reduced by the use of sensitive endpoints determined in previous studies and successfully applied to these tests, as allowed by USDA notice 04-09. All of the studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.101

APHIS 9 CFR 113.102

APHIS 9 CFR 113.103

APHIS 9 CFR 113.104

Category E Explanations

Registration Number: 22-R-0144

Number of Dogs: 2

Species (common name) dog of animals used in the study.

Explain the procedure producing pain and/or distress

Dogs listed in column E were used in a study required to optimize the challenge dose of a virus for a canine vaccine. The regulations require that the study be allowed to proceed until the dogs develop significant clinical signs of the disease..

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results.

The dogs were observed carefully every day for clinical signs of the disease after challenge to allow humane intervention and euthanasia if dogs developed severe clinical signs of the disease. The disease progressed rapidly, and two dogs developed acute terminal complications. This study was reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

The study was required to support requirements of 9CFR 113.306.

Category E Explanations

Registration Number: 22-R-0144

Number of 3

Species (common name): Dogs used in the study.

Explain the procedure producing pain and/or distress

The three dogs were involved in Antigen Dose-finding of 6-month Duration of Immunity for Rabies ORA-DPC Vaccine in dogs by serology.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The animals develop acute terminal complications related to testing before any veterinary intervention was possible.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.209

Category E Explanations**Registration Number:** 22-R-0144**Number of Guinea Pigs:** 752**Species (common name).** Guinea Pig of animals used in the study.**Explain the procedure producing pain and/or distress**

Guinea Pigs (n = 752) listed in column E were used in the regulatory required potency testing of commercial bacterins. The potency tests were conducted as required by Federal regulations. Guinea pigs became sick and developed signs and/or local irritation due to the bacterial challenge.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The effects of analgesic or anti-inflammatory medication on the length and severity of the disease has not been known; thus, use of medications would invalidate the scientific value of the potency test. For this reason, neither the USDA/CVB nor our company have used any medications to reduce pain and distress. USDA/CVB regulations do not allow the use of any other standard potency test for the quality control release of these bacterin products as no alternative potency test has been validated and accepted by the USDA/CVB. In April 2011, we validated the use of an analgesic in the potency test for one product and implemented drug in use in June 2011 after USDA approval. We are in the process of developing regulatory acceptable in vitro testing that will reduce or eliminate the use of guinea pigs. All studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.106
APHIS 9 CFR 113.107

OCT 18 2013

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0148/Invivoteck
2. Number 181 of animals used in this study.
3. Species (common name) Hamster of animals used in the study.
4. Explain the procedure producing pain and/or distress.

The animals are being utilized to study the pathogenic bacterium *Clostridium difficile*, the most common cause of diarrhea in hospitalized patients. Ninety-percent of *C. difficile* infections are associated with current or recent use of antibiotics. As a model of human disease, the animals are administered clindamycin by a subcutaneous injection and subsequently inoculated with the *C. difficile* organism by oral gavage. Within 48 hours animals begin showing signs and symptoms of disease, including diarrhea (i.e. "wet tail") as well as reduced activity, responsiveness and feeding. Animals are monitored three times daily during this period of time and animals in obvious distress are humanely euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

We explored the possibility of using medication to relieve animal suffering. However, the use of opioids can cause constipation, nausea and weight loss (Thomas. 2008. J. Pain Symptom Manage. 35:103-13) which would confound our observations of diarrhea and weight loss which are used to assign moribund status. Similarly, treatment of diarrhea with anti-diarrheals (e.g. bismuth) would interfere with the onset of diarrhea and confound assignment of moribund status. Therefore, we utilized frequent observation combined with an objective scoring system to assign moribund status and perform humane euthanasia on animals in distress. This strategy allows us to obtain scientifically meaningful data from the studies while simultaneously limiting animal suffering to a minimum.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

Attachment 1**Explanation for Animals Listed in Category E-APHIS Form 7023: FY 2013**

Registration Number 22-R-0149

Customer number 328985

Testing of proprietary compounds is conducted in animals to discover, develop, and manufacture therapeutics for animal health and human health and in response to federal requirements. On occasion, the proprietary compounds cause unexpected pain or distress which cannot be foreseen, but which is nevertheless considered during the review and approval process of the IACUC. In addition, federally mandated challenge models can result in pain and distress. Frequently, the use of pain relieving drugs is not scientifically appropriate in product assessment.

These studies are designed in accordance with the safety testing guidelines described in the following publications:

(b) (4)



3. Code of Federal Regulations-Title 21, Part 511-New Animal Drugs for Investigational Use and Part 514 (New Animal Drugs for Investigational Use Application) and resultant Center for Veterinary Medicine guidance.

(b) (4)



Each of the following Animal Use Procedures (AUPs) involved studies in which animals could have experienced pain and/or distress. In the course of developing animal health therapies and vaccines, animal models mimicking clinical disease are required to assess product efficacy. In addition, known vaccines are required to be tested with mandated challenges. Any incident of pain or distress was limited in duration to that scientifically necessary, and in each explanation noted below, the absolute minimum number of animals was used. Where euthanasia was required, it was conducted in a manner approved by the IACUC for the particular study. In addition, the IACUC conducts post-approval monitoring of approved Animal Use Procedures, and emphasizes continuous efforts to refine humane endpoints, where appropriate.

There are also occasions when pain-relieving drugs cannot be used in drug discovery studies. Pain and distress may result during the evaluation of efficacy in novel entities, as there may be limited information on how the new therapeutic reacts in the live animal. These studies serve as the basis for subsequent pivotal dossier studies. Pain-relieving drugs were not used because they would have adversely affected the scientific validity of the study, and any incident of pain or distress was limited in duration to that scientifically necessary. The animals that experienced unrelieved pain and/or distress in discovery studies are included in the explanations.

Attachment 1

Explanation for Animals Listed in Category E-APHIS Form 7023: FY 2013

Registration Number 22-R-0149

Customer number 328985

Species: Dogs

A. One discovery study objective was to assess the efficacy of analgesic compounds [REDACTED]. Twenty-eight (28) dogs remained on study and experienced varying degrees of pain/lameness. [REDACTED] the animals returned to full weight bearing within twenty-four to forty-eight hours post injections. In this model, administration of analgesics (other than those being tested) is not possible during the testing regiment, as they may alter the response of the animal to the test compound and adversely affect the scientific validity of the study. Nursing and supportive care are provided, and post-procedural analgesics are provided by the veterinary staff, as indicated.

B. One discovery study objective [REDACTED]. One (1) dog was found deceased one day after dosing. The animal was under veterinary oversight and was not observed to exhibit clinical signs.

C. Four (4) dogs were used [REDACTED] to evaluate the efficacy of novel therapeutic compounds. Reactions in these animals following compound administration were stiffening/flexing when handled and tremors. In this discovery model, pain relieving drugs were not used because they could have adversely affected the scientific validity of the study. The animals remained on study with supportive care under veterinary oversight and were euthanized within one (1) day of onset of the clinical signs.

Species: Cats

D. One discovery study objective was to assess the efficacy of analgesic compounds [REDACTED]. Two (2) cats remained on study and experienced varying degrees of pain/lameness. [REDACTED] and animals returned to full weight bearing within forty-eight hours post injection. In this model, administration of analgesics (other than those being tested) is not possible during the testing regimen, as they may alter the animal's response to the test compound and adversely affect the scientific validity of the study. Administrations of analgesics, as well as other nursing and supportive care, are provided post-procedurally by the veterinary staff, as indicated.

NOV 15 2013

Attachment 1

Explanation for Animals Listed in Category E-APHIS Form 7023: FY 2013

Registration Number 22-R-0149

Customer number 328985

Species: Guinea Pigs

E. The study objective was to determine [REDACTED] in guinea pigs as outlined in code of Federal Regulations (CFR) [REDACTED]. The tests are required [REDACTED]. Two hundred and sixty-eight (268) animals experienced acute systemic toxic effects and died during the study. Use of drugs may invalidate the scientific validity of the results as per CFR regulations.

F. The study objective was [REDACTED]

The test is required [REDACTED]

[REDACTED] Fourteen (14) animals experienced acute systemic toxic effects and died during the study. Use of analgesics or other pain-relieving agents could defeat the objectives of the study by directly interfering with the end point parameter being measured falsely implying that the antigen fluids have been inactivated.

Species: Hamsters

G. The study objective was to determine [REDACTED]

[REDACTED] The tests are required by regulation as proof of vaccine potency in each serial of vaccine produced. Three thousand one hundred and fifty-four (3,154) animals experienced acute systemic toxic effects and died during the conduct of the study. Use of drugs may invalidate the scientific validity of the results per CFR regulations.

H. The study objective was to determine [REDACTED]

[REDACTED] Sixty (60) animals experienced acute systemic toxic effects and died during the conduct of the vaccination and challenge study. Use of drugs may invalidate the scientific validity of the results.

Attachment 1

Explanation for Animals Listed in Category E-APHIS Form 7023: FY 2013

Registration Number 22-R-0149

Customer number 328985

Other Animals

Species: Horses

I. Sixty-four (64) horses were used in a FDA-approved procedure [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] These horses experienced a local reaction to the adjuvant administered. They remained on protocol while appropriate supportive care and veterinary oversight was provided. [REDACTED]

[REDACTED] does not permit any deviation during the course of the protocol, including the administration of analgesics, systemic symptomatic or therapeutic treatment due to the possible residual contamination of the final blood product.

Summary of IACUC Approved Exceptions to the Standards and Regulations for APHIS Form 7023: FY 2013

Registration Number 22-R-0149

Customer number 328985

- The IACUC approved an exception to the sanitation period such that primary enclosures were not cleaned and sanitized every two weeks, which involved ninety-six (96) dogs for 42 days. This was to ensure that no cross-contamination occurred between treatment groups [REDACTED] as well as to minimize stress involved in moving animals that had been [REDACTED]. If cross contamination occurred, the study integrity could be compromised and the study could need to be repeated, which would require the use of additional animals. Pens were washed down each day, food bowls and enrichment items were sanitized on schedule, the veterinary staff monitored the living conditions, and there was felt to be minimal impact on overall animal health.
- The IACUC approved a similar exception to the sanitation period which involved forty-eight (48) cats for up to 56 days. This was to ensure that no cross-contamination occurred between treatment groups [REDACTED] as well as to minimize stress involved in moving animals that had been [REDACTED]. If cross contamination occurred, the study integrity could be compromised and the study could need to be repeated, which would require the use of additional animals. Pens were washed down each day, food bowls and enrichment items were sanitized on schedule, the veterinary staff monitored the living conditions, and there was felt to be minimal impact on overall animal health.

**Summary of IACUC approved Canine Exercise Exemptions
USDA Registration No. 22-R-0009**

Protocol Title	Number of animals	Days Without Exercise	Reason
(b) (4)	10	7-20 days per study	(b) (4)
(b) (4)	28	3-20 days	(b) (4)

**Summary of IACUC approved Nonhuman Primate Housing Exceptions
USDA Registration No. 22-R-0009**

Protocol Title	Number of animals	Days Without Social Housing	Reason
(b) (4)	18	7-23 days per study	(b) (4)

To: USDA-APHIS

From: Princeton University

Registration Number: 22-R-0022

Re: Listing of IACUC Approved Exceptions to standards and regulations under the Act

Following the IACUC Policy, 3 nonhuman primates were exempted from the minimum requirements for water by IACUC approval for research purposes involving motivation of learning behavior.

Appendix 2
BMS IACUC Exemption Report for 2013
Customer # 168; Research Facility Certificate # 22-R-0028



B. Summary of exceptions to the regulations and standards October 1, 2012 - September 30, 2013Exceptions to the social housing aspect of the nonhuman primate Environmental Enrichment Program

In all of the following cases, monkeys were housed in visual, auditory and olfactory contact with conspecifics and were allowed to take part in all other aspects of the environmental enrichment program, such as interacting with manipulanda and receiving food treats.

Thirty-seven non-human primates (NHPs) were granted exceptions from the social housing aspect of the environmental enrichment program for EEG recording studies requiring animals to operate touch screens for cognitive training. Animals had 8 to 36 occurrences of individual housing for periods ranging from 24 hours to 14 consecutive days. In addition, 41 NHPs on telemetry studies were granted exceptions from the social housing program to avoid interference problems engendered by cohousing. These animals had 1-4 occurrences of single housing with each occurrence lasting 2 to 43 days.

Forty-nine NHPs were granted exceptions from the social housing aspect of the environmental enrichment program for the conduct of pharmacokinetic studies. These studies involved the use of radiolabeled compounds and required the use of special cages for the collection of excreta (urine and feces). The NHPs remained in these special collection cages until the radioactive levels of the excreta reached normal levels. The single housing periods lasted between 2 and 12 days. Each NHP was involved in 4 or fewer studies. At the end of the studies, animals were returned to their normal social housing conditions.

Twenty-six NHPs were granted exceptions from the social housing aspect of the environmental enrichment program for 6-12 months for the conduct of studies requiring animals to operate touch screens. The studies required single housing conditions to allow detailed observations and the accomplishment of motor tasks.

Eleven NHPs were granted exceptions from the social housing aspect of the environmental enrichment program for the purpose of toxicity studies requiring single housing for up to 2 weeks to allow individual observation of physical and neurological signs.

Exceptions to the Dog Exercise Program

In both of the following cases, the dogs were housed in cages which met 100% of the dogs' space requirement and had visual, auditory and olfactory contact with conspecifics.

Three dogs were considered as exceptions to the exercise program for a 7 day pharmacokinetic study involving radiolabeled compounds and the collection of excreta (urine and feces).

Twelve canines were considered as exceptions to the exercise program for pharmacokinetic studies requiring the collection of excreta (urine and feces). A total of 4 studies lasting 4 days and 1 study lasting 9 days were conducted.

Other exceptions

Thirty nine dogs were considered as exceptions to the standard 2-week complete kennel sanitation program for the conduct of nose touch screen studies. The sanitation of these cages was performed every 16 to 29 days and up to 12 occurrences were noted. However, the standard daily cleaning of the kennels was maintained during this period.

B) Summary of IACUC-approved exceptions to the Standards and Regulations:

35 dogs were exempted from the exercise requirement for 10 days during recovery from a surgical procedure.

27 dogs were exempted from the exercise requirement for 14 days during recovery from a surgical procedure.

18 dogs were exempted from the exercise requirement for 18 days during individual fecal sample collection.

14 dogs were exempted from the exercise requirement for 10 days during individual telemetry collection.

3 dogs were exempted from the exercise requirement for 2 days during individual telemetry collection.

1 dog was exempted from the exercise requirement for 4 days during individual telemetry collection.

1 dog was exempted from the exercise requirement for 8 days during individual telemetry collection.

Exceptions to Regulations:

Registration Number: 22-R-0144

Exceptions to the regulations and standards specified and explained by the principal investigator and approved by the IACUC.

Forty-four dogs were used in studies involving challenge with a contagious and hardy virus. For biosafety concerns and to avoid cross-contamination the dogs were exempted from the exercise program for up to 22 days. The caging was in full compliance and provided 100% of the required space. The IACUC reviewed and approved the exception and the study

What, if any, federal regulations require this procedure?

The studies were required by 9CFR 113.317, 9CFR 113.317 and Veterinary Services Memorandum 800.202, section 4.5, to support licensure of a new vaccine.